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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/806,636	05/23/2001	Iwao Yamaguchi	FJIN	3336

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[REDACTED] EXAMINER

OH, SIMON J

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1615

DATE MAILED: 08/21/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)
	09/806,636	YAMAGUCHI ET AL.
	Examiner Simon J. Oh	Art Unit 1615

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-24 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The inclusion of the parenthetical entry in the claim renders it to be of improper form. It is unclear as to whether the language of entry is intended to be part of the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (e) the invention was described in–
 - (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
 - (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

2. Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Inaba *et al.* (U.S. Patent No. 6,040,434)

The Inaba *et al.* patent teaches a drug composition comprising AZT and an aldehyde oxidase inhibitor (See Abstract; and Column 2, Lines 29-32). Examples of the aldehyde oxidase

inhibitor include esculetin (See Column 2, Lines 40-47). The drug composition, which may also contain pharmaceutically acceptable salts of the aldehyde oxidase inhibitor, is preferably in the form of a sustained release formulation (See Column 3, Lines 4-8; and Column 3, Line 64 to Column 4, Line 30).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Inaba *et al.*

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The Inaba *et al.* patent teaches a drug composition comprising AZT and an aldehyde oxidase inhibitor (See Abstract; and Column 2, Lines 29-32). Examples of the aldehyde oxidase inhibitor include esculetin (See Column 2, Lines 40-47). The drug composition, which may also contain pharmaceutically acceptable salts of the aldehyde oxidase inhibitor, is preferably in the

form of a sustained release formulation (See Column 3, Lines 4-8; and Column 3, Line 64 to Column 4, Line 30).

4. Claims 1-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Savastano *et al.* (U.S. Patent No. 5,681,584) in view of Watanabe *et al.* (U.S. Patent No. 5,455,268) and Hashimoto *et al.* (U.S. Patent No. 5,574,062)

The Savastano *et al.* patent teaches a pharmaceutical composition that provides for the controlled continuous release of an active agent. This composition preferably releases 70% to 100% of the active agent within 24 hours of ingestion (See Abstract; and Column 5, Lines 45-57). Active agents suitable for use in the composition include 5-lipoxygenase inhibitors (See Column 6, Line 35). The composition comprises an enteric coating, which may be made from materials including cellulose acetate phthalate, hydroxypropylmethylcellulose phthalate, and methacrylic acid copolymer (See Column 11, Lines 30-43). Hydroxypropylmethylcellulose and ethylcellulose may be included in the composition for a variety of functions, including binders (See Column 8, Lines 1-4) and as materials used in a delay coating (See Column 8, Lines 36-41). Ethylcellulose is also disclosed as a preferred material for a semi-permeable membrane (See Column 10, Lines 13-16). Examples are also given which outline the mass quantities of the components of the composition (See Examples 1, 3, and 4).

The Savastano *et al.* patent does not teach a controlled-release composition specifically comprising esculetin or its derivatives, nor does it disclose release properties of the composition defined in terms of plasma concentration.

The Watanabe *et al.* patent teaches compositions comprising esculetin and its derivatives, which include compounds of the same general formula as that claimed by the applicant, where groups R¹ and R² are independently an hydrogen atom, a saturated or unsaturated aliphatic acyl group having 2 to 25 carbon atoms, or a benzoyl group; and where group R³ is an hydrogen atom or an alkyl group (See Column 2, Lines 3-17). Esculetin and its derivatives may be used interchangeably in a pharmaceutical composition (See Claim 1).

The Hashimoto *et al.* is relied upon merely as a teaching reference, establishing esculetin as an inhibitor of 5-lipoxygenase (See Column 2, Lines 62-64).

It would be obvious to one of ordinary skill in the art to combine the teachings of Savastano *et al.*, Watanabe *et al.*, and Hashimoto *et al.* into the objects of the present invention. The Savastano *et al.* patent teaches the composition, and discloses that 5-lipoxygenase inhibitors may be used in the composition. Hashimoto *et al.* discloses esculetin as a specific example of a 5-lipoxygenase inhibitor, and Watanabe *et al.* discloses esculetin and its derivatives, which may be used interchangeably in a pharmaceutical composition. One of ordinary skill in the art would be motivated to prepare an esculetin composition as taught by Savastano *et al.*, merely as a specific embodiment of the invention disclosed therein. One of ordinary skill in the art would be motivated to use an esculetin derivative in the composition as taught by Savastano *et al.*, based on the disclosure of Watanabe *et al.* of the interchangeability of esculetin and its derivatives in a pharmaceutical composition. Regarding the claim limitations drawn to release properties of the composition defined in terms of plasma concentration, it is the position of the examiner that formulating a composition demonstrating such features would be within the purview of one of ordinary skill in the art through routine experimentation, given the disclosure of the prior art.

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The patentability of such claim limitations are not considered novel absent a showing of criticality or of unexpected results. Thus, the claimed invention as a whole is *prima facie* obvious.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (703) 305-3265. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Simon J. Oh
Patent Examiner
AU 1615

sjo
August 16, 2002


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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